

It was asserted that the new process claims directed to the manufacture of an intraocular lens was not originally claimed because the original claims directed to the process were dependent from a product or article claim.

The Applicant traverses this decision. The withdrawal of these claims from consideration after the first action on the process does not comply with either 37 CFR 1.142(b) or MPEP § 821.03. Clearly, the original claims directed to the process were searched, examined and considered in the first office action. It is indifferent to this issue the fact that the original process claims in a European format were dependent from the article claims. It is also noted that the application is based on a PCT application and the article claims and process claims in a PCT application for making the same article cannot be objected to as a separate and distinct invention. The Applicant therefore requests an action on the merits of claims 44-63 along with proposed new process claim 65 which replaces claim 60.

2. Claim rejections - 35 U.S.C 102

Claims 19-21, 23, 34 and 27-33 were rejected under 35 U.S.C 102(b) as being anticipated by Vanderbilt (U.S. No. 5,326,306).

Claims 19-23, 26-32 were further rejected under 35 U.S.C 102(b) as being anticipated by Bos et al. (U.S. No. 5,762,836).

According to amended claim 19, there is provided an intraocular lens which is comprised of a flexible material. The intraocular lens has at least one relatively rigid portion, which is a chemical structural modification of the flexible material to impart relative rigidity. Such a structure is therefore devoid of fusion or assembly zones used to join two distinct materials which have been contemplated or used in the past to produce bimaterial lenses.

Contrary to the Response to Arguments in paragraph 9 of the outstanding office action, this claim is not directed to a product by process as it relies on structural features, namely, the rigid portion being a chemical

structural modification of the flexible material. Moreover, even if this claim were considered to be a product by process claim, it is not the process features which are relied on but rather the structure of the lens which results from a process, namely the chemical structural modification of the flexible material. The Examiner points out that whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In the instant application, the process leads to the obtention of a product which is structurally different from the products obtained by the prior art processes.

Therefore, the claimed intraocular lens differs from the prior art lenses, not only because it is obtained by a different process, but because this different process leads to a structural modification which was not obtained by the prior processes.

Accordingly, it is believed that the claimed intraocular lens is patentable *per se* in view of the prior art. It is clear that no prior art teaches or suggests a lens made of flexible material and having a rigid portion which is a chemical structural modification of the flexible material.

According to amended claim 20, a feature of this chemical structural modification is recited, namely the covalent bonds between the at least one relatively rigid portion and the unmodified flexible material. In this respect, it is pointed out that in the various examples of the application, there is flexible material, for example a hydroxymethylmethacrylate containing polymer which has hydroxyl groups and the flexible material and the rigidified flexible material are bonded by covalent bonds which is the result of a chemical reaction of the hydroxyl groups with the flexible zones with a reactive compound. No such covalent bonds are between the rigidification flexible material is disclosed in the prior art.

The physical characteristics of the claimed optical lens are therefore different from those of the prior art.

It is recalled that the specification discloses two major ways of obtaining such a device. One involves submitting the flexible material to a chemical modification, whereby the chemically modified zone becomes rigid while the non-modified portion remains flexible. The other involves submitting the flexible material to a chemical modification and thereafter copolymerizing the unsaturated bonds with additional monomers.

Examples of these two ways of modifying the flexible zone in order to impart rigidity thereto are illustrated in Annexes 1 and 2. In both cases, the chemical modifications, with optional further copolymerization, result in both a chemical structural modification and the formation of covalent bonds on the rigid zone which initially was flexible material too.

An example of the structure of the material resulting from the second way is illustrated in Annex 3.

As shown in this example, the copolymers are formed in the presence of methyl methacrylate, butyl methacrylate and ethyleneglycol methacrylate, leading to a polymer network optionally reinforced by PMMA, which after polymerization constitutes the material constituting the attachment members of the implant.

The prior art fails to teach or suggest the claimed features of the present intraocular lens.

Vanderbilt discloses a process of interpenetrating two preexisting polymeric networks, whereby a **physical** assembly occurs between the rigid zone and the flexible zone.

The junction of the two zones is performed as follows :

- 1) a central rod made of flexible material is machined in order to obtain a desired diameter,
- 2) the material is thereafter swelled by addition of a hydrophobic monomer such as MMA, and then, in the mold, a reticulating agent and a free-radical initiator are added,
- 3) the mold is then placed at a high temperature, which allows the polymerization of the hydrophobic monomer and the reticulating agent.

This process leads to the formation of a double block, where the central block is constituted of a rigid material and the two parts of the block are linked together through the interpenetration of the polymeric networks. The rigid material is not a chemical structural modification of the flexible material, as required by claim 19, nor are there any covalent bonds between the rigid material and the flexible material.

According to Vanderbilt, the zones of interpenetration contain both flexible material and rigid material, whereas in the claimed invention, there is no zone of interpenetration including both rigid material and flexible material, the chemically structurally modified zone is imparted with rigidity while the unmodified zone remains flexible.

It is pointed out in Vanderbilt (see col. 8, lines 1-9) that "*a good bond, or adhesion, between the two dissimilar polymers layers*" is obtained because, according to the patentee, "*the MMA monomer of the cylindrical ring portion can then diffuse into the softened layer because the HEMA and MMA are miscible, and, upon polymerization of the MMA, an interpenetrating polymer network forms at the interface*".

While in the case of monomer diffusion, the compatibility of the monomers with the material in which they diffuse is desired, this property allowing the diffusion is on the contrary not sought in the present invention.

The Vanderbilt process and structure are illustrated in Annexes 4 and 5.

Bos et al. is no more pertinent than the teachings of Vanderbilt. Bos et al. disclose a method of making an intraocular lens, where the optical part and the haptic part are mechanically bonded to each other during molding. The method is characterized by fitting together two solid parts. The attachment members previously formed of a rigid material (PMMA) are placed into a mold in which a mixture of monomers is poured, leading to a flexible material after polymerization.

As mentioned in the passage from col. 4 line. 66 to col. 5, line 14, the bonding may be obtained either mechanically, by interpenetration or by adhesion .

Bos et al. therefore do not disclose a rigid material which is a chemical structural modification of the flexible material or covalent bonds between the flexible material and the rigid material.

The optical lens obtained according to Bos et al . is illustrated in Annex 6.

3. Claim rejections - 35 USC 103

Claims 25 and 36 were rejected under 35 U.S.C 103(a) as being unpatentable over Vanderbilt '506 in view of Freeman et al. (U.S No.5 693 095).

The Examiner acknowledges that Vanderbilt fails to disclose diethyleneglycolmethacrylate as the polyfunctional agent but points out that Freeman et al disclose the use thereof for crosslinking polymers and that the use of such an alternative polyfunctional agent would have been obvious.

The Applicants reiterate and incorporate therein his position set forth in the response to the Office Action dated August 13, 2001.

Claims 34 and 35 were rejected under 35 U.S.C 103(a) as being unpatentable over Vanderbilt '506 in view of Scherr et al. (U.S No.3 391 224).

The Examiner acknowledges that Vanderbilt fails to disclose a polyfunctional crosslinking agent but points out that Scherr et al. disclose the use thereof in the production process of copolymers to provide a surface modification with long-term stability and that the use of such an alternative polyfunctional agent would have been obvious in the modification of the material to stabilize it.

Scheer et al. disclose a polyester resin composition for optical lenses comprising (1) the esterification product of fumaric acid, triethyleneglycol and 2-ethyl-1,3-hexanediol, ethyl-1,3-hexanediol or 2,2-dimethyl-1,3-propanediol, (2) methyl methacrylate, and (3) styrene, in defined proportion, where, as stated in col. 2, l. 13-14, "*The styrene aids the methylmethacrylate in converting the polyester to a thermoset formable condition*".

According to Scherr et al., the lenses made from this resin composition are haze-free, transparent, grindable, shatter-resistant and mar-resistant (col. 1, l. 39-42).

Scherr et al., however, do not disclose or suggest that styrene can be used in combination with other components, in order to structurally modify the surface of a flexible material in order to impart it with rigidity.

Claims 36-43 were rejected under 35 U.S.C 103(a) as being unpatentable over Vanderbilt '506 in view of Wang (U.S No.6 011 082).

The Examiner acknowledges that Vanderbilt fails to disclose a polyfunctional crosslinking agent but points out that Wang disclose the use thereof in the production process of copolymers to provide a surface modification with long-term stability and that the use of such an alternative

polyfunctional agent would have been obvious in the modification of the material to stabilize it.

Wang discloses a method for forming a surface modification on a polymer substrate where the polymer substrate is swelled with a mixture of monomers bearing functional groups which are able to modify the properties of the material, such as modifying the contact angle with water or the affinity for heparin. As stated in the passage from col. 2, line 65 to col. 3, line 62, this process involves the use of surface interpenetrating polymer networks .

Also, as stated at col 2., lines 54-57 : *"There are no direct bonds to any reactive groups located on the surface of the polymer surface"*.

Therefore, Wang does not teach or suggest the use of a multifunctional agent for imparting rigidity to a flexible material by use of a chemical modification or covalent bonds.

In view of the present amendment and the foregoing remarks, it is believed that this application has been placed in condition for allowance.

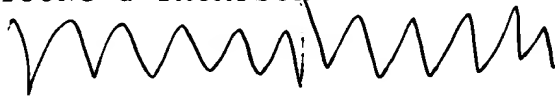
In the event that there are any questions relating to this amendment, it would be appreciated if the Examiner would telephone the undersigned attorney.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

Respectfully submitted,

YOUNG & THOMPSON

By



Robert J. Patch
Attorney for Applicants
Registration No. 17,355
745 South 23rd Street
Arlington, VA 22202
Telephone: 521-2297

November 12, 2002



VERSION WITH MARKINGS TO SHOW CHANGES MADE

19. (Amended). Intraocular lens, said intraocular lens being comprised of a flexible material, said lens having at least one relatively rigid portion, said flexible material of said at least one relatively rigid portion having a structural chemical modification to impart relative rigidity.

20. (Amended). Intraocular according to claim 19, wherein [the structurally modified flexible material defining] there are covalent bonds between the at least one relatively rigid portion [is chemically structurally modified flexible material] and the unmodified flexible material.

34. (Amended). Intraocular lens according to claim 33, wherein said reactive compound is a [monofunctional] monofunctional agent.

64. (New) Intraocular lens according to claim 42, wherein the monomers are selected from the group consisting of styrene, acrylic derivatives and alkylacrylic derivatives, and the polymer is PMMA.

65. (New). A process according to claim 61, wherein the monomers are selected from the group consisting of styrene, acrylic derivatives and alkylacrylic derivatives, and the polymer is PMMA.

RECEIVED

NOV 15 2002

TECHNOLOGY CENTER R3700